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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/647,543

10/02/2000

Heidi Sisniega Barroso

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EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/647,543	BARROSO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	James S. Ketter	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 18-34, 36, 37, 40-48 and 50-67 is/are pending in the application.
- 4a) Of the above claim(s) 6-15, 18, 27, 36, 37, 47 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 19-26, 28-34, 40-46, 48, 50-56 and 58-67 is/are rejected.
- 7) ☒ Claim(s) 2, 4 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Claims 6-15, 18, 27, 36-37, 47 and 57 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11 February 2005.

The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required.

The disclosure is objected to because of the following informalities: At page 2, line 20, there is an instruction, between arrows, to insert page 2a at that point. However, this is an improper amendment to the specification. If printed as a patent the text would likely be printed as it appears, complete with the double arrows and the inserted material remaining between the text of pages 2 and 3. Applicants should rewrite pages 2 and 2a to create a continuous block of text that reads as intended. Pages 3 and beyond may need to be renumbered if the text of pages 2 and 2a will not fit onto a single page

Appropriate correction is required.

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Claim 34 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 34 depends from 33 and 25, not in the alternative. Claims 65 and 66 are objected to because of the following informalities: The term “fungi” is plural; the singular, “fungus”, should be used instead to preserve the grammar of the sentence. Appropriate correction is required. Claims 2, 4 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 19-26, 28-34, 40-46, 48, 50-56, 58, 65 and 67 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record set forth in the previous Office Action, the rejection being maintained with respect to the phrase “a complementary strand”.

To clarify, “a complementary strand” is understood to include fragments of the opposite strand, i.e., to which they are complementary, as well as longer nucleic acids comprising such fragments. The instant claims continue to read on a very large genus of possible promoter nucleic acids. The phrase “having nucleotides 1-740 of SEQ ID NO:1” can be read as referring back to “a nucleotide sequence”. As such, the phrase “a complementary strand” would not be required to have all of nucleotides 1-740, and thus would have the meaning set forth above.

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Applicants argue extensively at the amendment filed 2 November 2005 that other sequences may be present in addition to the recited promoter sequence. However, it appears that Applicants are arguing under the presumption that the claims are limited to promoters comprising all of the nucleotides 1-740 of SEQ ID NO:1 or comprising all of the nucleotides of the full-length complement of nucleotides 1-740. However, as discussed above, the claim reads on embodiment comprising only a fragment of the complement of 1-740. There is inadequate written description for a promoter comprising only a fragment of nucleotides 1-740 of SEQ ID NO:1 in the absence of the remainder of nucleotides 1-740 of SEQ ID NO:1, i.e., the fragment is the only portion of SEQ ID NO:1 present. The specification has not set forth teachings to have permitted one of skill in the art to have known which regions of SEQ ID NO:1 were necessary for the disclosed function as a promoter. Furthermore, there was no theory or algorithm offered in the specification or the prior art permitting one of skill to know the structure-function relationship for the disclosed promoter. As such, one of skill would not have recognized that Applicants were in possession of the full scope of the claimed invention. It is only over these grounds that the present rejection remains in place.

Claim 66 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claim actually recites an accession number to which the claim would be limited. However, to practice the invention as drafted, one of skill would need the deposited material, not merely a copy thereof.

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Thus, the deposit would need to be perfected to overcome the instant rejection. **First**, however, a (re)consideration and review of the application and prosecution history leads to the conclusion that strain TGDTh-4 is enabled generally by the disclosure in view of the prior art. As such, the mere deletion of any reference to the accession number of the actual deposit itself in the instant claim would be sufficient to overcome the instant rejection. **Second**, alternatively, should Applicants wish to keep the accession number in the claim, the deposit must be perfected by the submission of a statement under 37 CFR §1.808(a)(2) assuring that "all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent."

Until either remedy is effected, the instant rejection stands.

The following are new grounds of rejection:

Claims 3 and 59-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to nucleic acids comprising a promoter from the *gdh* gene of a member of genus Aspergillus. A. awamori and niger *gdh* promoters have been disclosed, but neither Applicants nor the prior art have set forth sequences for the *gdh* promoters from

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other members of the genus. There are no teachings in the disclosure or the prior art which would have permitted one of skill to know the sequence, i.e., structure, of the other promoters, merely from their known function, as structure-function relationships of promoters was not well-enough characterized at the time of filing to permit this.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 65 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claim is drawn to a filamentous fungus expressing the promoter of claim 1, which promoter could be interpreted as being in its resident locus on the chromosome. Such would read upon wild-type Aspergillus awamori.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 65 is rejected under 35 U.S.C. 102(b) as being anticipated by Curtis et al.

As set forth above, in the rejection under §101, the strain of claim 65 encompasses wild-type Aspergillus awamori.

Curtis et al. simply shows that Aspergillus awamori was known in the prior art.

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Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jsk  
May 5, 2006



JAMES KETTER  
PRIMARY EXAMINER